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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,417	08/22/2001	Leon V. Rudakov	52200-8006.US01	9486

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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,417	RUDAKOV ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-16 have been canceled.

Claims 17-19 are pending.

Specification

The disclosure is objected to because of the following informalities: there does not appear to be a brief description of figures 9 and 10.

Appropriate correction is required.

Also, the specification does not indicate which parts are the Background, Brief Summary, etc. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 13 of U.S. Patent No. 6,371,980, in view of Bhatnagar, 5,958,428. Claims 1 and 13 of Patent 6,371,980 essentially recite all the limitations of claims 17-19, including an impervious polymer sleeve and a coating disposed on the inner and outer surfaces of the polymer sleeve for enhancing endothelial cell growth on the polymer sleeve. However, Patent 6,371,980 does not recite a first layer of free amine groups and a second linker layer between the first layer and the third cell adhesion peptide layer.

However, Bhatnagar teaches that the mode of attachment of a peptide to a solid phase can be covalent linkages such as by the addition of amino acids at either the N-terminus or C-terminus to provide for binding or conjugate of the peptide to the solid phase (see col. 10, lines 37-45). Bhatnagar also teaches that the necessary domain (i.e., the peptide to be bound to the support) may include spacer arms to facilitation binding (see col. 10, lines 51-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the linkage taught by Bhatnagar to bind the peptide in Patent 6,371,980 to the solid substrate because Bhatnagar teaches that this method of attachment provides the benefit of facilitating binding of the peptide to the support. The amino acids at the N-terminus, or alternatively the N-terminus disclosed by Bhatnagar is considered to be the claimed first layer that provides free amine groups. The spacer arm disclosed by Bhatnagar is considered to be the claimed second linker layer. (The molecules are considered to be in a layer because they are linking the peptide coating, or layer, to a substrate.) The spacer arm is in between the

peptide layer and the layer of amine groups because it is disclosed to be in the necessary domain, i.e., the peptide, (see col. 10, line 52), and also because Bhatnager discloses that additional amino acid residues or other moieties may be added to one or the other side of this domain to facilitate coupling or the like, so long as the essential cell-binding property of the domain is not substantially inhibited (col. 8, lines 1-3).

As to claim 18, it is a product by process claim and the product has been discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, or in the alternative, under 35 U.S.C. 103(a) as obvious over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, and further in view of Barone et al., 5,360,443.

Alcime et al. disclose the invention substantially as claimed. More specifically, as to claim 17, Alcime discloses an expandable support frame (i.e., stent, for example, reference 32, column 6, line 48) having first and second end portions, a polymer sleeve

(liner, for example, reference 34, column 6, line 53-55) having inner and outer surfaces, and a coating of a cell adhesion peptide (column 13, lines 56-61) carried on and attached to at least one of the inner and outer surfaces of the polymer sleeve for enhancing endothelial cell growth on the polymer sleeve.

However, Alcime et al. do not teach that the coating has a first layer that provides free amine groups, a second linker layer, wherein the linker layer is positioned between and covalently bonded to each of the first layer and the cell adhesion peptide coating/layer (a particular cell adhesion peptides is not yet claimed in claims 17 and 18).

However, Bhatnagar teaches that the mode of attachment of a peptide to a solid phase can be covalent linkages such as by the addition of amino acids at either the N-terminus or C-terminus to provide for binding or conjugate of the peptide to the solid phase (see col. 10, lines 37-45). Bhatnagar also teaches that the necessary domain (i.e., the peptide to be bound to the support) may include spacer arms to facilitation binding (see col. 10, lines 51-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the linkage taught by Bhatnagar to bind the Alcime et al. peptide to the solid substrate because Bhatnagar teaches that this method of attachment provides the benefit of facilitating binding of the peptide to the support. The amino acids at the N-terminus, or alternatively the N-terminus disclosed by Bhatnagar is considered to be the claimed first layer that provides free amine groups. The spacer arm disclosed by Bhatnagar is considered to be the claimed second linker layer. (The molecules are considered to be in a layer because they are linking the peptide coating, or layer, of the Alcime et al. peptide to a substrate.) The spacer arm is

in between the peptide layer and the layer of amine groups because it is disclosed to be in the necessary domain, i.e., the peptide, (see col. 10, line 52), and also because Bhatnager discloses that additional amino acid residues or other moieties may be added to one or the other side of this domain to facilitate coupling or the like, so long as the essential cell-binding property of the domain is not substantially inhibited (col. 8, lines 1-3).

As to the limitation regarding the sleeve being impervious, there is not recitation as to what the sleeve is impervious in the claims nor in the disclosure of Applicants' specification, and the dictionary definition of impervious does not imply that it is impenetrable by a particular material, such as water, but just that it is impenetrable (Merriam Webster's Collegiate Dictionary, Tenth Edition). Thus, the Alcime et al. sleeve (made of polymers disclosed in column 13, lines 35-42 designed to reduce the porosity of the stent) is considered to be impervious.

Alternatively, Alcime et al. do not specifically disclose that the sleeve is impervious. However, Barone et al. teach that an aortic graft (i.e., a stent, see fig. 1) can have a coating of biological inert material such as TEFLON or porous polyurethane (col. 7, lines 16-19), and Barone et al. also teach that because of the rapid flow of blood, it is preferred that the tube (160), (i.e., the graft, or stent, col. 5, lines 55-56) be made impervious when used for repairing aneurysms which have ruptured (col. 10, lines 29-32.) The TEFLON coating is not disclosed as being impervious. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide TEFLON (not disclosed as pervious or porous) as a coating on an aortic graft or stent

as taught by Barone et al., using the linking layers and peptide as taught by Alcime et al. and Bhatnagar, because Barone et al. teach that such a coating is an alternative to a porous polyurethane, and that an impervious material is preferred when using the device for repairing aneurysms which have ruptured, because of the rapid flow of blood.

Claim 18 is a product by process claim. The product is disclosed by Alcime (see above.)

2. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, and further in view of Brown et al., 6,071,305, (or in the alternative, under 35 U.S.C. 103(a) as obvious over Alcime et al., 5,632,772, in view of Bhatnagar, 5,958,428, and Barone et al., 5,360,443, and further in view of Brown et al., 6,071,305.)

Alcime et al. in view of Bhatnagar (alternatively, in view of Bhatnagar and Barone et al.) disclose the invention substantially as claimed (see above). More specifically, Alcime teaches an expandable stent for treatment of blood vessels, wherein the stent includes therapeutic drugs such as heparin, column 13, lines 56-61. However, Alcime does not teach that the cell-adhesion peptide has the amino acid sequence presented as SEQ ID NO:1. Bhatnagar teaches SEQ ID NO:1 as a synthetic peptide substitute for natural collagen, but Bhatnagar does not teach that the synthetic peptide is used in stents such as that disclosed in the Alcime et al. reference.)

However, Brown et al. teach the use of therapeutic drugs such as heparin or *collagen on a stent* (column 2, lines 38-52, column 5, line 17 and 26).

Moreover, Bhatnagar further teaches that collagen functions as a structural protein of tissues and that it is the major fibrous element in blood vessels, see column 1, lines 50-53, and that collagen participates in physiological interactions which include formation of complexes with other macro-molecules such as fibronectin and the modulation of cell proliferation, see column 2, lines 24-31. Bhatnagar further discloses that collagen appears to cause adverse reactions within the body, and thus synthetic peptides are provided that mimic the cell binding domain of collagen, see column 3, lines 21-32. Bhatnagar teaches that the synthetic peptide has the amino acid sequence as disclosed in column 3, lines 42-43, which is the same amino acid sequence as Applicant's claimed SEQ ID NO:1.

Since both Alcime et al. and Brown et al. references teach the use of providing a therapeutic drug such as heparin or other drugs on a stent, and Brown et al. further teach that the drug may also be collagen, it would have been obvious to provide collagen as the therapeutic drug in the Alcime et al. stent with the polymer sleeve, as would be desirable for providing the benefit of a therapeutic effect as taught by Brown.

Furthermore, it would have been obvious to provide, on the Alcime et al. stent, the synthetic peptide disclosed by Bhatnagar, as an alternative to natural collagen, because it provides the advantage of obtaining the same therapeutic effect as natural collagen but without the adverse effects of natural collagen, as taught by Bhatnagar. Moreover, the skilled artisan would have reasonable expectation of success in utilizing the Bhatnagar synthetic collagen because Brown et al. teach that collagen may be provided on stents and the skilled artisan would expect that the synthetic collagen would

also be capable of being attached to a stent, given the methods of attachment disclosed by Bhatnagar as described above.

Response to Arguments

Applicants' arguments filed November 22, 2006 have been fully considered but they are not persuasive.

The 112, second paragraph rejection in the previous Office action is hereby withdrawn in view of the amendment to the claims

Applicants state that in view of the amendment to the claims to include an impervious polymer sleeve, withdrawal of the rejection is requested. However, as noted above, there is not recitation as to what the sleeve is impervious in the claims nor in the disclosure of Applicants' specification, and the dictionary definition of impervious does not imply that it is impenetrable by a particular material, such as water, but just that it is impenetrable (Merriam Webster's Collegiate Dictionary, Tenth Edition). Thus, the Alcime et al. sleeve (made of polymers disclosed in column 13, lines 35-42 designed to reduce the porosity of the stent) is considered to be impervious.

As an alternative grounds for rejection, it was stated above that Alcime et al. do not specifically disclose that the sleeve is impervious but that Barone et al. teach the motivation to utilize a impervious sleeve (as discussed more fully above.)

Lastly, the previous claims recited a porous sleeve rather than an impervious sleeve but an obviousness double patenting rejection could have been made. The

present action is made non-final to give Applicants an appropriate opportunity to respond to the obviousness double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2/19/07

ANN YEN LAM
PATENT EXAMINER